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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,499

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Hans-Axel Hansson

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Aibihns.Zacco AB
P.O. Box 5581
Valhallavagen 117
STOCKHOLM, SE-114 85
SWEDEN

EXAMINER

DOUGHERTY, SEAN PATRICK

ART UNIT

PAPER NUMBER

3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,499	Applicant(s) HANSSON, HANS-AXEL	
	Examiner SEAN P. DOUGHERTY	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 9-11 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/01/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the initial Office action based on the 10/598499 application filed 09/01/2006. Claims 1-18 are currently pending and have been fully considered below.

Priority

This application claims priority to PCT/SE05/00295 filed 03/02/2005. PCT/SE05/00295 is noted as claiming priority to US Provisional Patent Application Number 60/521193, filed 03/08/2004.

Copies of the certified copies of the priority documents (PCT/SE05/00295) have been received in this nation stage application from the International Bureau (PCT Rule 17.2(a)).

Information Disclosure Statement

The information disclosure statement(s) (IDS) submitted on 09/01/2006 is/are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement(s) is/are being considered by the Examiner.

Election/Restrictions

Claims 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/04/2009.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

The following claims are objected to because of the following informalities:

Claim 2 recites the limitation(s) "the flow rate and the flow direction" at line 2;

Claim 4 recites the limitation(s) "the flow path" at line 2;

Claim 5 recites the limitation(s) "the operation" at line 3;

Claim 8 recites the limitation(s) "the delivery end" at lines 3-4;

Claim 9 recites the limitation(s) "it" at line 4;

Claim 12 recites the limitation(s) "the capability" at lines 3 and 3; and

Claim 13 recites the limitation(s) "the action" and "the active" at line 4.

There is insufficient antecedent basis for this/these limitation(s) in the claim(s) because the limitation(s) has/have not been previously recited in the claim(s).

Claim 6 reads the limitation "means.." at line 2 and should read --means.--

Claims 9, 10, 11 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12, 14 and 15 rejected under 35 U.S.C. 102(b) as being WO 01/78591 to Blake et al. (hereinafter "Blake", cited in IDS).

Regarding claim 1, Blake discloses an automatic system for taking of a fluid sample from a sample site of a living text object, comprising:

- catheter means comprising a three-way junction (junction formed generally around element 22; best seen in Figures 4A-4N) configured to be located in proximity to the sample site (12), the three-way junction is connected to a first catheter means (stretching from element 28 to element 22), a second catheter means (stretching from element 22 to generally around element 24) and a sample-taking end (16);
- a valve (30) connected to the first catheter means, the valve having an inlet (catheter located below element 30) for an immiscible fluid to be aspirated into the first catheter means ("air bubble" best seen aspirated in Figure 4E), and
- pumping means (32) connectable to the catheter means and configured to aspirate an amount of the immiscible fluid into the first catheter means (pg. 10, ll. 10 and 16-22) and to move the amount of the immiscible fluid to the three-way

Art Unit: 3736

junction (pg. 10, ll. 24-26) and arrange a first part of the immiscible fluid (right portion of element 72 best seen in Figure 4E) in a part of the second catheter means (best seen in Figure 4G) and a second part of the immiscible fluid (left portion of element 72 best seen in Figure 4E) in a part of the first catheter means (best seen in Figure 4G);

- whereby the first and second parts of the immiscible fluid being configured to separate a taken sample from the rinsing fluid (best seen in Figure 4H; pg. 10, ll. 26-31).

Regarding claim 2, Blake discloses where the pumping means further being configured to control the flow rate and the flow direction of a fluid comprised in the catheter means such that the fluid flow can pass by the sample-taking end when flowing from one of the first and second catheter to the other. Note that fluid (the "airbubble") can be seen as passed by the sample-taking end when flowing from the first catheter as best seen in Figure 4G. Therefore, since this limitation is accomplished, the pumping means of Blake is clearly is configured to control the flow rate and the flow direction of a fluid comprised in the catheter means since the fluid flow passing the sample taking end is achieved.

Regarding claim 3, Blake discloses where the sample-taking end is configured to be placed at the sample site (note sample-taking end 16 at the sample site 12 as best seen in Figures 4A-4N), where the pumping mean being configured to move the first part of the immiscible fluid towards an end opening of the sample-taking end (the end opening is considered the area generally around element 22 where the first and second

Art Unit: 3736

catheter means meet) and to take a fluid sample when the first part is located at the end opening (note the "airbubble" is located at the end opening as best seen in Figure 4G, and where the pumping means is configured to transport the taken sample from the sample-taking end (best seen in Figure 4I) to a sample-delivery end (26) configured to deliver the taken sample to a sample tube (70).

Regarding claim 4, Blake discloses a plurality of valves (30/20/24) arranged at the catheter means and configured to control the flow path of the fluid in the catheter means.

Regarding claim 5, Blake discloses a control unit (58) connectable to the pumping means and the plurality of valves (best seen in Figure 2) and configured to control the operation of the pumping means and the plurality of valves.

Regarding claim 6, Blake discloses a double lumen catheter means - the Examiner notes the catheter below valve 30 is a first catheter and the catheter below valve 20 is a second catheter, making two, or double lumens.

Regarding claim 7, Blake discloses a source of rinsing fluid (36) connectable to the catheter means (best seen in Figures 4A-4N) and configured to supply a rinsing fluid from the source to the catheter means.

Regarding claim 8, Blake discloses where the pumping means are configured to provide a flow of rinsing fluid from the source of rinsing fluid through the catheter means to a waste tube at the delivery end of the catheter means - the Examiner notes the pumping means is seen providing the rising fluid from the source of the rinsing fluid through the catheter means to a waste tube (26) as best seen in Figures 4A-4N.

Art Unit: 3736

Regarding 12, Blake discloses where the pumping means is configured as one single double-acting suction and force pumping means with a first part (32) having the capability of providing a pushing action and a second part (56) having the capability of providing a suction action, and where the first and second parts further configured to operate simultaneously or separately (pg. 35, ll. 22-24).

Regarding claim 14, Blake discloses analyzing means configured to analyze the taken fluid sample.

Regarding claim 15, Blake discloses a source of a drug solution ("acid wash" pg. 9, ll. connectable to the catheter means, the pumping means being configured to transport an amount of the drug to the sample-taking end and supply the drug to the sample site.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736